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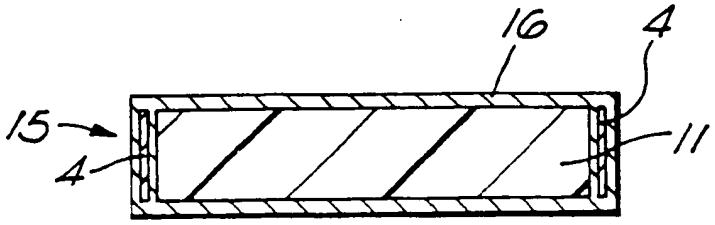

(57) Abstract

An artificial spinal disc comprises a body (15) of a moulded polyurethane elastomer (16) having a circumferential reinforcement in the form of a band (4) of net material and having an internal space filled with pliable material (11).

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ARTIFICIAL SPINAL DISC

The present invention relates to an artificial spinal disc and a method of making an artificial spinal disc.

In the medical field, for research and teaching purposes and for use in practising surgical techniques, there is a need for an artificial spinal disc. Such a disc can either be used as such or several can be included in an artificial spine. In the latter case, the key to simulation of the accurate movement of the different sections of the spine is the production of working artificial intervertebral discs which must be securely attached top and bottom to the vertebrae as in life. Thus when the spine is flexed, the discs are extended or retracted.

According to the present invention from one aspect, there is provided an artificial spinal disc comprising a body of moulded elastomeric material.

According to the present invention from another aspect, there is provided a method of making an artificial spinal disc, comprising moulding elastomeric material to form a body.

Said elastomeric material preferably comprises a polyurethane elastomer.

Preferably, the body includes a circumferential reinforcement, for example a band of reinforcing material such as net material. Preferably, said reinforcement is such that it is less stretchable in the circumferential direction of the body than orthogonal to that direction.

Said body could be formed with an internal space, which space could be filled with a pliable material, which pliable material could comprise cured elastomeric material for example.

The body is preferably made using the steps of:-

applying elastomeric material to at least a base of a cavity having the general shape of a spinal disc;

receiving a plug inside said cavity;

applying elastomeric material into a space between said plug and a side wall of the cavity;

removing said plug;

at least partially filling said cavity with a support material; and

applying elastomeric material over said support material.

In this case, said elastomeric material could be applied over said support material by covering said cavity with a mould portion and applying elastomeric material between said mould portion and the cavity and over said support material.

Said support material could also provide such pliable material.

The present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figures 1 to 3 illustrate the production of a band of reinforcing material for use in an artificial spinal disc, Figure 4 illustrating the stretchability of the band;

Figures 5 to 11 illustrate steps in the production of the disc; and

Figure 12 is a cross-section through the finished disc.

To produce a simulated, artificial spinal disc according to one example of the present invention, first (referring to Figure 1) a piece 1 of fisherman's net is pinned to a frame 2 so that it is stretched under tension in one direction. The stretched piece 1 is then starched so that the result is that it will stretch substantially no more in the direction in which it was stretched but will do so in the orthogonal direction.

Referring to Figure 2, a template 3 having a shape which corresponds to the circumferential profile of a spinal disc is then laid on to the piece 1 of net, extending longitudinally in the direction in which the piece 1 was stretched. The outline of the template 3 is then drawn on to the piece 1 and then the outline is cut around to produce a reinforcing band 4 for the artificial spinal disc - see Figure 3. Alternatively, a die is made of the patterns of several reinforcing bands and several such bands are stamped out at a time using the die. A band 4 represents the annulus of a spinal disc and it allows the disc wall to stretch superiorally/inferiorally but substantially not to extend its perimeter - see Figure 4 in which the band 4 can stretch in the directions of arrows Y but substantially cannot stretch in the directions of arrows X.

A polyurethane elastomer is then painted (or injected) over the base and side wall of a cavity 5 of a mould 6 (see Figure 5), the cavity 5 generally having the shape of a spinal disc. The reinforcing band 4 is then laid in around the side wall of the cavity 5 - see Figure 6. Then, a lid 7 having a plug 8 is carefully fitted on to the mould 6 (see Figure 7), the plug 8 being somewhat smaller than the cavity 5 with the band 4 in it, to enable a hollow shape to be cast. Referring to Figure 8, with the lid 7 tied to the mould 6, the polyurethane elastomer is injected via a syringe 9 through one of two

holes 10 in the lid 7 until the space between the plug 8 and the band 4 is full. Before application of elastomer as described above, the mould is sprayed with release agent.

After the polyurethane elastomer has set, the lid 7 is removed and a mixture 11 of a polyurethane elastomer and plasticizer (such as that sold under the trade name "Flabbercast" by B.J.B. Enterprises, Inc., of 13912 Nautilus Drive, Garden Grove, California 92643, USA) is poured into the hollow cavity defined by the set polyurethane elastomer to within about 2mm from the top - see Figure 9. When the mixture 11 has cured, a generally flat lid 12 having a shallow cavity 13 in the general shape of a vertebra is carefully fitted on to the mould 6 with the cavity 13 overlying the now filled cavity 5 - see Figure 10. With the lid 12 tied to the mould 6, the polyurethane elastomer is injected via the syringe 9 through one of the holes 14 in the lid 12 until the space above the cured mixture 11 is full (see Figure 11), the cured mixture 11 providing support material for this step.

After the polyurethane elastomer has set, the lid 12 is removed and the body 15 in the cavity 5 is removed. Figure 12 is a section through an artificial spinal disc manufactured according to the foregoing, reference numeral 16 denoting the polyurethane elastomer. The set mixture 11 now serves as pliable material inside the artificial disc.

The body 15 is now usable as an artificial spinal disc, for example in an artificial spine (see below), for the purposes of demonstrating the structure of a spinal disc itself, and to simulate the properties of such a disc as found in life. For demonstrating disc structures in different age groups, for example, such bodies 15 may be filled with different mixtures 11, of different cured hardnesses.

A simulated, artificial spinal disc in the form of a body 15 may also be used to demonstrate a prolapsed and herniated disc by making it so that a certain amount of the cured mixture 11 can escape through the disc's side wall in the form of a bladder when under pressure. When pressure is released, the mixture 11 is retracted back into the disc to re-establish normal anatomy.

Rings of elastomer could be added to the body 15 to simulate a degenerated disc as found in injury or the aged.

There will now be described how an artificial spine can be made using discs made as described above.

First, to make a mould, components as follows are taken and assembled so as to be anatomically correct:

24 vertebrae; 1 sacrum and coccyx; and the base of the skull, all moulded in silicone rubber and cast in polyurethane. (The bones).

1 section the length of the spine, of extruded plastics material 17 millimetres in diameter, which represents the spinal cord.

23 intervertebral discs running from C1 to S1.

A modelling wax is then laid over the components, to represent connecting ligaments and spinal nerves. The assembly is then moulded in silicone rubber and surrounded with an epoxy resin case to produce a silicone rubber mould.

To manufacture the artificial spine, a fresh set of bones is taken together with hollow artificial discs made as described above. Both the articulating surfaces of the artificial discs and the bodies of the vertebrae are painted with primer and allowed to dry. The discs are

inserted between the vertebrae and elastomer is painted between the primed surfaces and allowed to dry. The whole spine with such an extruded plastics "spinal cord" in place is put into the mould. The mould is closed and elastomer is injected. The result is an articulated spine with simulated ligaments and nerves made of flexible elastomer, the resulting model having the dynamics of a human spine and the degree of movement being dependent on the flexibility of the particular contents 11 of the discs. Such an artificial spine can be used to demonstrate both the properties of a human spine and those of discs themselves of such a spine.

CLAIMS

1. An artificial spinal disc comprising a body of moulded elastomeric material.

2. A disc according to claim 1, wherein said elastomeric material comprises a polyurethane elastomer.

3. A disc according to claim 1 or 2, wherein the body includes a circumferential reinforcement.

4. A disc according to claim 3, wherein said reinforcement comprises a band of reinforcing material.

5. A disc according to claim 4, wherein said band comprises a band of net material.

6. A disc according to claim 3, 4 or 5, wherein said reinforcement is less stretchable in the circumferential direction than orthogonal to that direction.

7. A disc according to any preceding claim, wherein said body is formed with an internal space.

8. A disc according to claim 7, wherein said internal space is filled with a pliable material.

9. A disc according to claim 8, wherein said pliable material comprises cured elastomeric material.

10. A disc according to any preceding claim, in an artificial spine.

11. Use of a body comprising moulded elastomeric material for the purpose of simulating the behaviour of a spinal disc.

12. A method of making an artificial spinal disc, comprising moulding elastomeric material to form a body.

13. A method according to claim 12, wherein said elastomeric material comprises a polyurethane elastomer.

14. A method according to claim 12 or 13, comprising the step of including a circumferential reinforcement in the forming of said body.

15. A method according to claim 14, wherein said reinforcement comprises a band of reinforcing material.

16. A method according to claim 15, wherein said reinforcing material comprises a band of net material.

17. A method according to claim 14, 15 or 16, including the step of treating said reinforcement so that it is less stretchable in the circumferential direction of the body than orthogonal to that direction.

18. A method according to any of claims 12 to 17, wherein said body is formed so as to have an internal space.

19. A method according to claim 18, wherein said internal space is filled with a pliable material.

20. A method according to claim 19, wherein said pliable material comprises cured elastomeric material.

21. A method according to any of claims 12 to 20, comprising the steps of:-

applying elastomeric material to at least a base of a cavity having the general shape of a spinal disc;

receiving a plug inside said cavity;

applying elastomeric material into a space between said plug and a side wall of the cavity;

removing said plug;

at least partially filling said cavity with a support material; and

applying elastomeric material over said support material.

22. A method according to claim 21, as dependent on claim 17 or 18, wherein said support material provides said pliable material.

23. A method according to claim 21 or 22, wherein said elastomeric material is applied over said support material by covering said cavity with a mould portion and applying said elastomeric material between said mould portion and the cavity and over said support material.

24. A method according to any of claims 21 to 23, as dependent on any of claims 14 to 17, wherein said reinforcement is applied around a side wall of said cavity after applying said elastomeric material to at least the base of the cavity and before receiving said plug inside said cavity.

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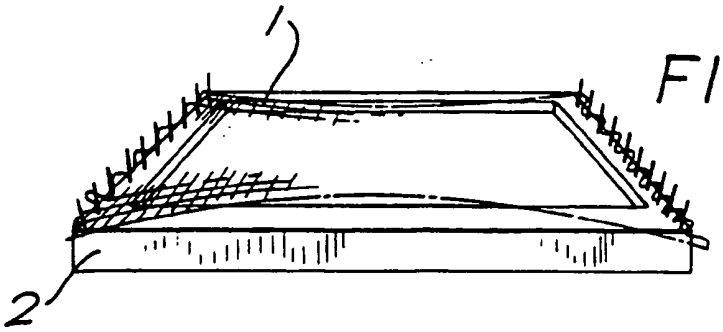


FIG. 1

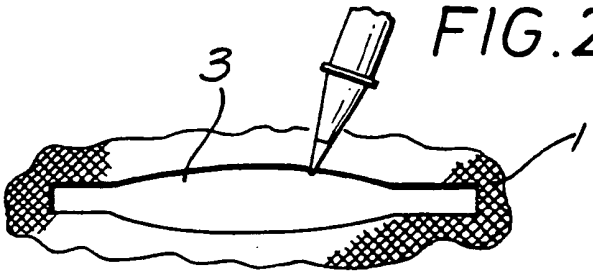


FIG. 2

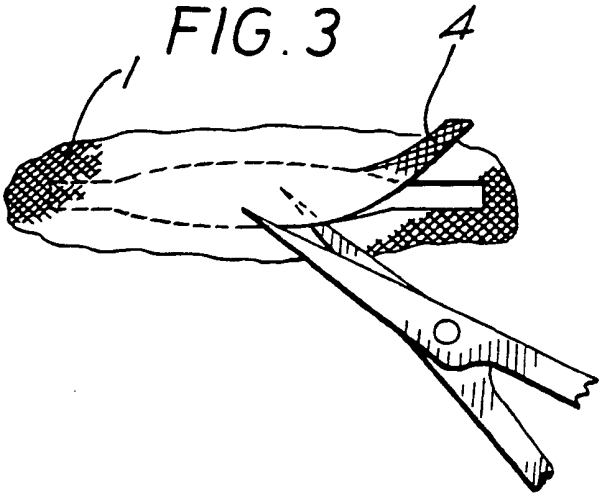


FIG. 3

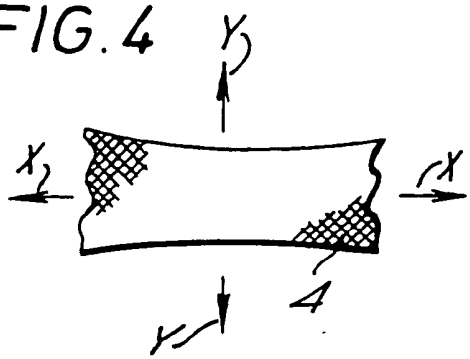


FIG. 4

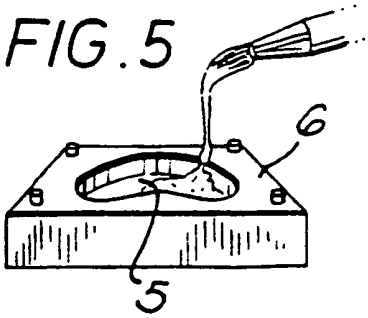


FIG. 5

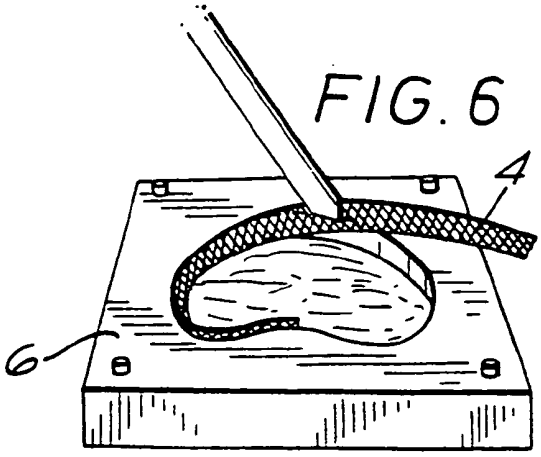


FIG. 6

FIG. 7

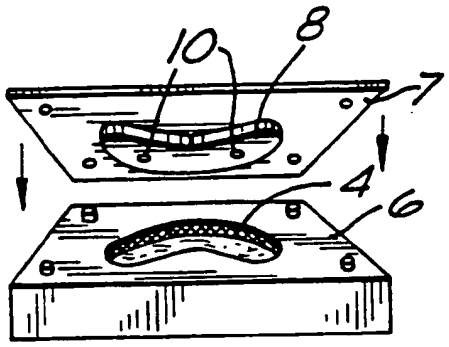


FIG. 8

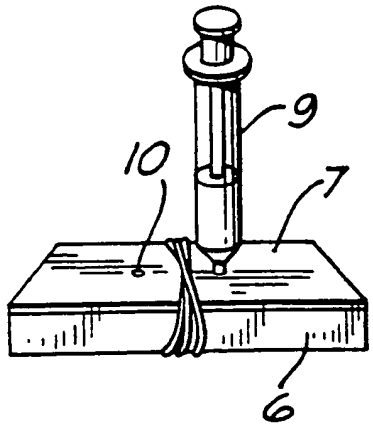


FIG. 9

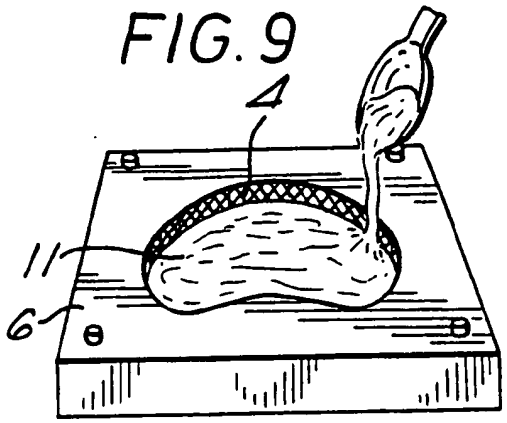


FIG. 10

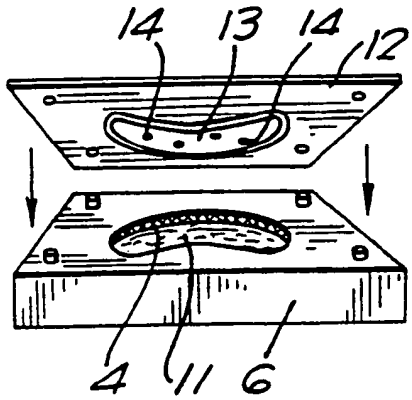


FIG. 11

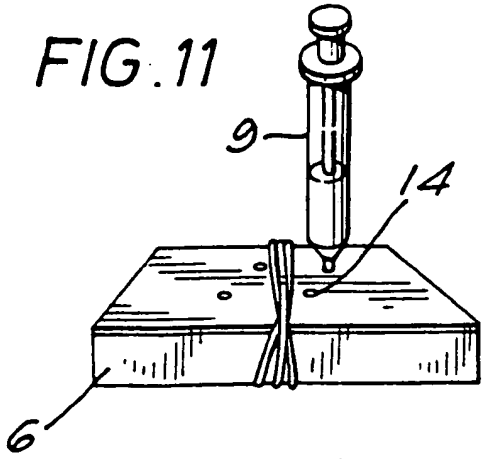
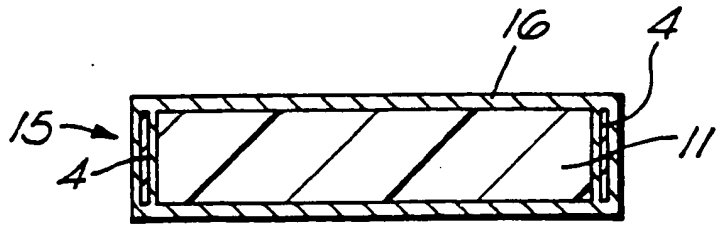


FIG. 12



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 93/00386

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F2/44; G09B23/32

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61F ; G09B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X Y	EP,A,0 346 129 (JOHNSON & JOHNSON) 13 December 1989 see the whole document	1-5,7-12 6
Y	EP,A,0 277 282 (SULZER) 10 August 1988 see column 3, line 41 - line 49; figures 1,2	6
X	US,A,3 762 070 (CULVER) 2 October 1973 see abstract; figures	11
A	US,A,3 867 728 (STUBSTAD) 25 February 1975	-
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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
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International Searching Authority	**Signature of Authorized Officer**
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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

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